

### REMARKS

Claims 1-28 are pending in the application. No claims are amended in this response.

The claims remain rejected under 35 U.S.C. §103(a) as unpatentable over U.S. Patent No. 5,487,901 ("Conte") in view of U.S. Patent No. 6,599,284 ("Faour"). The rejection is traversed.

The Examiner acknowledges that Conte does not teach or suggest a laser incision for releasing an active agent from a pharmaceutical tablet but alleges that Conte discloses a pharmaceutical tablet composed of an upper layer containing an active ingredient, formulated for immediate release, an intermediate layer formulated with polymers as a semipermeable membrane that does not contain an active agent, and a lower layer of the same formulation as the upper layer containing identical or different active agents and being almost completely coated with an insoluble polymeric coating. According to the Examiner, Faour discloses a controlled release osmotic device comprised of an outer layer or external coating containing active ingredients, an intermediate layer forming a semipermeable membrane and an inner layer or core containing active ingredient. The Examiner additionally states that the dosage form comprises a passageway formed by a laser incision and that it would have been obvious to a person of ordinary skill in the art to disclose a tablet system comprising two external layers and a third layer with laser incisions on the surface as taught by Conte in view of Faour.

Applicants disagree because the references teach contrasting methods for releasing an active agent from a formulation.

Conte describes a predetermined passageway characterized by the use of a semipermeable membrane in which an active agent is released through the passageway. The drilling scheme used by Conte avoids exposing a large surface of the film (and of the tablet) to a laser energy source that has the risk of inducing degradation of the tablet. Conte additionally

uses an osmotic pump designed to capture and entrap fluids and, through swelling of certain ingredients, release an active substance. Importantly, the active agent is released by dissolution.

In contrast, an active agent in the Faour system is released by erosion when the system expels particles. The system from Faour is designed to accommodate a gradual increase in the size of a passageway with a progressive opening of the passage way by opposing a push pull system. There is no layer providing power to expel an active agent. Therefore, it would be difficult, if not impossible to get all drug released without an increase in the size of the passage way. The osmotic pump taught by Faour thus provides low "push" and it becomes difficult to expel through a small hole. The decrease of push is compensated by increasing the size of the passage way that assists in expelling the drug. At the same time a larger passageway allows an external hydrodynamic effect from fluids entering not through the semi permeable membrane but through the passageway.

The artisan would not turn to Faour to modify Conte because using a laser incision as taught by Faour would frustrate the dissolution profile established in the tablet system taught in Conte. The artisan would have considered a laser as taught by Faour to undermine and frustrate Conte's osmotic pump system for releasing an active agent. Therefore, these references are not combinable to produce the claimed invention.

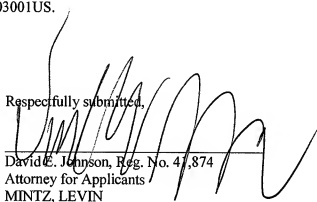
To this extent the references teach away from one another. The Court of Appeals for the Federal Circuit stated in *McGinley v. Franklin Sports* (262 F.3d 1339, 2001):

As a "useful general rule,"... references that teach away cannot serve to create a *prima facie* case of obviousness. In *re Gurley*, 27 F.3d 551, 553, 31 USPQ2d 1131, 1132 (Fed. Cir. 1994). If references taken in combination would produce a "seemingly inoperative device," ... such references teach away from the combination and thus cannot serve as predicates for a *prima facie* case of obviousness. In *re Spinnoble*, 405 F.2d 578, 587, 160 USPQ 237, 244 (CCPA 1969) (references teach away from combination if combination produces seemingly inoperative device); see also In *re Gordon*, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984) (inoperable modification teaches away).

Accordingly, Conte and Faour cannot be combined to produce the claimed invention for at least these reasons. Applicants request reconsideration and withdrawal of the rejection and request a Notice of Allowance.

Applicants submit that the application is in condition for allowance and request an action for same. A petition for an extension of time and Notice of Appeal accompany this response. Please charge any additional fees due, or credit any overpayment of same, to Deposit Account 50-0311, Attorney Reference No.: 28069-503001US.

Respectfully submitted,



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